

## REMARKS

**Office action summary.** Claims 1-13, 16, 17, 20-26, 28, 30 and 32-49 are rejected as obvious over U.S. Patent No. 5,890,490 (“Aylsworth”). Claims 14-15 are rejected as obvious over Aylsworth in view of U.S. Patent No. 6,616,606 (“Peterson”). Claims 18 and 19 are rejected as obvious over Aylsworth in view of a purported admission of prior art. Claims 27 and 29 are rejected as obvious over Aylsworth in view of U.S. Patent 6,763,832 (“Kirsch”). Claim 31 is rejected as obvious over Aylsworth in view of U.S. Patent No. 7,225,829 (“Bowen”).

Applicants appreciate the withdrawal of the prior enablement rejection.

These rejections are traversed.

**Obviousness over Aylsworth.** The obviousness rejection admits that Aylsworth does not disclose the claimed “exclusion” of exclude any means for automatically adjusting the rate of fluid flow. (Action at 2.) The Action states, however, that this deficiency in Aylsworth does not matter for obviousness. It relies on a case, *In re Karlson*, 136 USPQ 184 (CCPA 1963), which purportedly stands for the view that “omission of an element and its function in a combination where the remaining elements perform the same functions as before involves only routine skill in the art.”

The reasoning of the Action is incorrect for a number of reasons.

To begin with, “the use of *per se* rules is improper in applying the test for obviousness under 35 U.S.C. 103.” MPEP § 2116.01. Courts have rejected *per se* rules of obviousness on many occasions, as cited for example in MPEP § 2116.01. A *prima facie* case of obviousness can only be made out by applying the test of *Graham v. John Deere*, not by applying a *per se* rule gleaned from some very old case (especially one that predates *Graham v. John Deere*, as *Karlson* does).

In addition, the Office itself has not subsequently read *In re Karlson* in the manner that the Action is reading it. For example, a panel of the Board of Appeals has written:

As to the view that it would have been obvious to modify Frantz in the proposed manner by the examiner because it would merely involve the elimination of the cycled operation with the consequent loss of function of the cycled operation, it is true that in *In re Karlson*, 311 F.2d 581, 584, 136 USPQ 184, 186 (CCPA 1963) the Court stated that “omission of an element and its function in a combination is an obvious expedient if the remaining elements perform the same functions as before.” The Court recognized, however, that this is not a mechanical rule, and that such language in *Karlson* was not intended to short circuit the determination of obviousness mandated by 35 U.S.C. § 103.

*In re Love*, Appeal No. 1999-1960 (PTO Bd. of Appeals & Interferences 2000).

Third, in this case the omission of automatic control is in the context of medical treatment. Traditionally it was felt that the administration of oxygen needed to be under the control of medical personnel. For this reason, the machines used for the medical administration of oxygen were based on systems other than patient control.

The present invention is based on a medical discovery, which is that patient control of administration can be clinically beneficial. In particular, the following classes of patients find that control of the rate of fluid flow is of benefit to them:

- Patients who require a high oxygen flow which a prior art system would not deliver because of the automatic adjustment features.
- Patients who do not generate a significant negative nasal pressure, which is employed by prior art systems to trigger fluid flow. This is particularly true if the patient breathes through his/her mouth with exertion. Therefore, the oxygen which the patient requires is not released.
- Patients who find the pulsing of oxygen resulting from the prior art systems' automatic adjustment mechanisms too uncomfortable to use. (FIG. 8 of Aylsworth shows an oxygen pulsing system, discussed starting at col. 7, line 49.)
- Patients who would prefer to raise the oxygen flow rate in anticipation of activity requiring high exertion rather than waiting for a system to detect that exertion and raise the flow for them

Clinical experience shows that the patients in these classes collectively form a significant fraction of those patients that require gas administration. This medical discovery in turn led to the design of a system capable of meeting the requirements of these classes of patients, one that would give them control of the flow.

Fourth, the method claims 44-48 reflect most directly the medical innovation in the present invention. Claim 44 directly recites as a method step the fact that the patient is in control, using a remote controller. Aylsworth does not teach such patient control. Claim 44 expressly recites patient control by means of a remote controller. No use of such controller by a patient is disclosed in Aylsworth.

The teachings of Aylsworth emphasize a "prescription" for gas which the patient must comply with (see, e.g., col. 1, lines 12-35), whereas the methods of claims 44-48 foresee that the patient will understand his or her own needs, given adequate training, and will have control over the flow of oxygen or other gas. Indeed, Aylsworth *teaches away* from the patient control

recited as a method step in claims 44-48 and as the purpose of the remote control unit in the remaining claims. Aylsworth states at the end of the background section that “once the patient leaves the controlled setting of the hospital, it is difficult to monitor the patient’s use of the oxygen to ensure that the [patient] is complying with the prescription.” (Col. 1, lines 32-35.) This is the “problem” Aylsworth was trying to solve – the fear that the patient might not comply. An elaborate system is implemented to monitor compliance. This teaches away from a system like that of the present invention, which places control in the patient’s hands and trusts the patient to adjust the flow. (A patient would be given training both in how to use the device and in what appropriate flows are for particular conditions.)

Fourth, while the Action says (p. 3) that the “electronic flow management module” 35 in Aylsworth is the claimed remote control, it would not appear from Aylsworth that this electronic control meets the claim limitation “to allow a user to adjust the rate of fluid flow from the source through the tube to the site” (claim 1) or the analogous limitation in claim 43. A search for all occurrences of “module 35” in the text of Aylsworth reveals no mention of that function. When there is a discussion of changing the operation of module 35 in Aylsworth the word “programmed” is used (e.g., col. 8, lines 33-34), strongly suggesting that the hospital and not the user changes whatever functions of module 35 change in Aylsworth.

Finally, the remainder of Aylsworth’s system would not work “perform the same functions as before” even if they were adapted (via impermissible hindsight reconstruction) to operate in accordance with the present invention. The controls which Aylsworth has, essentially designed for communication with a hospital, would not be appropriate for a patient controlled system.

For all of these reasons, the Action fails to make out a prima facie case of obviousness of the rejected independent claims over Aylsworth.

**Purported admission of prior art** (page 5 of Action). Applicants noted in a prior response that voice recognition technology existed at the time of the present invention. The present applicants were not the first to invent voice recognition. That statement does mean that voice recognition was “conventional” (a term of imprecise meaning) but only that it would have been possible for a person of skill in the art, who had the idea of using voice recognition in the context of the present invention, to figure out how to implement voice recognition in that context by referring to prior art knowledge.

The statement made by applicants regarding voice recognition does not imply that any and all claims reciting the use of voice recognition are obvious. “Virtually all inventions are necessarily combinations of old elements. The notion, therefore, that combination claims can be declared invalid merely upon finding similar elements in separate prior patents would necessarily destroy virtually all patents and cannot be the law under the statute, Sec. 103.” *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1575 (Fed. Cir. 1987) (footnotes omitted). Instead, in order to make out a prima facie case of obviousness, the Examiner should show that the criteria for combining two references, as set out in the MPEP, are met.

**Dependent claim 28.** Dependent claim 28 recites that “the valve provides a substantially constant flow rate of the breathable gas to the individual.” In embodiments of the invention addressed by this claim, the system helps the user by maintaining the flow rate which the user has chosen. While the Action indicates (at page 2) that this claim is obvious over Aylsworth, no reasoning is given in support of this statement nor is any citation given to any place where Aylsworth discloses a substantially constant flow rate of the fluid.

Aylsworth seems in fact to teach away from a substantially constant fluid flow. Aylsworth instead discloses a valve 13 which appears to take on only two positions, “energized” and “de-energized.” See, e.g., col. 2, lines 3-7 (“The control valve is switchable between a first position wherein the gas from the source of gas passes through the monitor to be breathed in by a patient and a second position wherein atmospheric air or gas passes through the monitor to be breathed in by the patient.”); col. 8, lines 1-7; FIG. 1. With such a valve having two positions it would be difficult to maintain a substantially constant fluid flow, and there is certainly no disclosure in Aylsworth that this is attempted. In addition, when Aylsworth discusses what happens when the flow goes outside a range prescribed by the hospital, reference is made to an “alarm” going out (col. 7, lines 41-48) and not to any effort to maintain a constant flow.

**Remaining rejections.** The rejections over Aylsworth in view of other references are inappropriate, at a minimum, because the invention as claimed is not obvious over Aylsworth.

**Conclusion.** If the Examiner has any questions about this response, it is respectfully requested that he telephone the undersigned attorney.

Respectfully submitted,

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